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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,758	06/16/2000	MASANOBU HOKASE	1241.15	4802

7590 07/26/2002
FITZPATRICK CELLA HARPER & SCINTO
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NEW YORK, NY 10112-3801

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/26/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,758

Applicant(s)

HOKASE, MASANOBU

Examiner

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/2002 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The phrase, "method for preventing mastitis" is not enabled by the instant specification.

Applicant on page 1 of his own specification admits that "[n]o effective method for preventing and treating mastitis has been established because of the difficulties in preventing and treating mastitis by pharmaceuticals or vaccination."

Thus, the instant specification establishes that mastitis is very difficult to treat let alone prevent. Applicant has shown examples in the specification which show administering phytase to dairy cows, but do not conclusively show that phytase has been prevented. Applicant has shown that phytase may be treated, but not prevented.

The art of biotechnology is very unpredictable especially in the administration of enzymes to treat diseases which have no known cure. The prevention of a disease such as mastitis, which as applicant has admitted has no known cure, is thus very incredible, since the converse has been admitted by applicant himself. Thus, applicant needs to provide further evidence showing conclusively that mastitis can be totally prevented *in vivo*.

Without such evidence the claims are not enabled by the instant specification.

Claims 9, 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term, "lactating cows" does not find support in the instant specification. It is not clear where applicant believes such support is in the instant specification. Without such support, the term introduces new matter into the application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase, "A method treating mastitis" is not grammatically correct. It would be clearer if applicant stated, "A method for treating mastitis".

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Lyons or Bedford et al.

The references each teach phytase being administered to cows/cattle. Since phytase is being administered to the cows which are "dairy cows" since they can give milk, then inherently the process is being performed as claimed.

Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Clarkson et al. or Morgan et al.

The references each teach phytase being administered to cows/cattle. Since phytase is being administered to the cows which are "dairy cows" since they can give milk, then inherently the process is being performed as claimed.

Claims 9, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards, Jr.

The reference eaches teach phytase being administered to cows/cattle. Since phytase is being administered to the cows which are "dairy cows" since they can give milk, then inherently the process is being performed as claimed.

The feed being administered in the reference would be considered to be a formula feed, see Table 1. The feed contains between 30-600 units of phytase per kilogram of feed, see col. 8, lines 20-31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons, Clarkson et al., Morgan et al., or Bedford et al. in view of Edwards, Jr. and CN 1135297 (CN).

The teachings of the primary references are above.

They do not teach using the specific amounts of phytase, that zinc methionine sulfate is added to the feedstuff or that the mammals (cows/cattle) suffer from mastitis.

The teachings of Edwards, Jr. and CN are of record.

It would have been obvious to use the claimed amount of phytase since Edwards makes it clear that such amounts are commonly used when administering phytase to cows in feedstuffs. It also would have been obvious to use zinc methionine sulfate since CN makes it clear that zinc methionine sulfate is a common feed additive for animals and that it has the advantages of the feed being prepared from readily available raw materials, saves food and has an obviously improved effect over other feeds. Further, it would have been obvious to use such a feedstuff to treat animals suffering from mastitis since many cows develop mastitis regularly and it would be inevitable that the farmer who feeds all of his cows with the feedstuff will also feed cows with mastitis and thus they will be treated.

Claims 1-3, 7-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards, Jr. in view of CN 1135297 (CN).

Edwards does not teach using zinc methionine sulfate in the feedstuff or that the mammals (cows/cattle) suffer from mastitis.

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The teachings of CN are of record.

It would have been obvious to use zinc methionine sulfate since CN makes it clear that zinc methionine sulfate is a common feed additive for animals and that it has the advantages of the feed being prepared from readily available raw materials, saves food and has an obviously improved effect over other feeds. Further, it would have been obvious to use such a feedstuff to treat animals suffering from mastitis since many cows develop mastitis regularly and it would be inevitable that the farmer who feeds all of his cows with the feedstuff will also feed cows with mastitis and thus they will be treated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

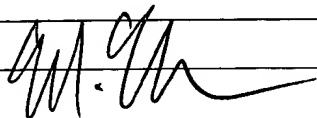
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Michael V. Meller

Examiner

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MVM

July 16, 2002